notice. This notice solicits comments on an information collection to meet specified requirements for submitting adequate and well-controlled studies to provide substantial evidence of effectiveness for a new animal drug.

DATES: Submit written or electronic comments on the collection of information by January 2, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substantial Evidence of Effectiveness of New Animal Drug—21 CFR 514.4(a) (OMB Control Number 0910–0356)—Extension

Section 512(d)(1)(E) of the Federal Food Drug and Cosmetic Act (the act) (21 U.S.C. 360b(d)(1)(E)) requires FDA to issue an order refusing to approve a New Animal Drug Application (NADA), if there is a lack of substantial evidence that a new animal drug will have the effect it is purported or represented to have under the conditions of use prescribed in the proposed labeling. Therefore, substantial evidence must be submitted to us as part of the NADA to establish effectiveness of a drug. Section 514.4(a) specifies requirements for submitting adequate and well-controlled studies to provide substantial evidence of effectiveness for a new animal drug. This information collection requirement provides for submissions of substantial evidence of effectiveness information via electronic submissions to the Center for Veterinary Medicine.

We are continuously seeking ways through advances in information technology to reduce the burden on the government and sponsors. We are continuing to look at what information can be submitted electronically and will permit electronic submission of data to NADA files as technology and resources permit.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
514.4(a)	190	4,546	860	632.6	544,036

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate for the annual reporting burden for this collection of information was derived from discussion with industry and agency records.

Dated: October 27, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18432 Filed 11–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0430]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection related to general licensing provisions for biologics license applications (BLAs), changes to an approved application, labeling, revocation and suspension, postmarketing studies status reports, and Forms FDA 356h and 2567.

DATES: Submit written or electronic comments on the collection of information by January 2, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567 (OMB Control Number 0910–0338)—Extension

Under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).

Section 130(a) of the Food and Drug Administration Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision (section 506B of the act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the agency to make publicly available information that pertains to the status of these studies.

Under section 506B(a) of the act, applicants that have committed to conducting a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated.

Section 601.2(a) requires a manufacturer of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under §§ 610.60, 610.61, and 610.62. The estimate for these regulations is included in the estimate under § 601.2(a) in table 1 of this document.Section 601.5(a) requires a licensee to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the licensee to notify selling agents and distributors upon suspension of its license, and provide FDA of such notification.

Section 601.12(a)(2) requires, generally, that the holder of an approved BLA must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires, generally, that the applicant must promptly review all promotional labeling and advertising to make it consistent with any labeling changes implemented. Section 601.12(a)(5) requires the applicant to include a list of all changes contained in the supplement or annual report; for supplements, this list must be provided in the cover letter. The burden estimates for § 601.12(a)(2) are included in the estimates for supplements (§ 601.12(b) and (c)) and annual reports (§ 601.12(d)). The burden estimates for § 601.12(a)(4) are included in the estimates under 601.12(f)(4) (Form FDA 2567) in table 1 of this document or OMB control number 0910–0001 (expires May 31, 2008) since the required information can also be submitted with Form FDA 2253.

Section 601.12(b)(1) and (b)(3), (c)(1) and (c)(3), (c)(5), and (d)(1) and (d)(3) require applicants to follow specific procedures to inform FDA of each change, in the product, production process, quality controls, equipment, facilities, responsible personnel or labeling established in an approved license application. The appropriate procedure depends on the potential for the change to have a substantial, moderate, or minimal adverse effect on the identity, strength, quality, purity, or potency of the products as they may relate to the safety or effectiveness of the product. Under § 601.12(b)(4), an applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship of the applicant. The burden estimate for § 601.12(b)(4) is minimal and included in the estimate under § 601.12(b)(1) and (b)(3) in table 1 of this document.

Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval before distributing the product. Section 601.12(f)(1), (f)(2), and (f)(3) requires applicants to follow specific procedures to report labeling changes to FDA. Section 601.12(f)(4) requires applicants to report to FDA advertising and promotional labeling and any changes.

Under § 601.14, the content of labeling required in § 201.100(d)(3) must be in electronic format and in a form that FDA can process, review, and archive. This requirement is in addition to the provisions of §§ 601.2(a) and 601.12(f). The burden estimate for § 601.14 is minimal and included in the estimate under § 601.2(a) (BLAs) and 601.12(f)(1), (f)(2), and (f)(3) (supplements and annual reports) in table 1 of this document.

Section 601.45 requires applicants of biological products for serious or life-threatening illnesses to submit to the agency for consideration, during the pre-approval review period, copies of all promotional materials, including promotional labeling as well as advertisements.

In addition to §§ 601.2 and 601.12, there are other regulations in parts 640, 660, and 680 (21 CFR parts 640, 660, and 680) that relate to information to be submitted in a license application or supplement for certain blood or allergenic products: §§ 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 660.51(a)(4), 680.1(b)(2)(iii), and 680.1(d). In table 1 of this document, the burden associated with the information collection requirements in these regulations is included in the burden estimate for § 601.2 and/or § 601.12. A regulation may be listed under more than one section of § 601.12 due to the type of category under which a change to an approved application may be submitted.

There are also additional container and/or package labeling requirements for certain licensed biological products: § 640.70(a) for Source Plasma; § 640.74(b)(3) and (b)(4) for Source Plasma Liquid; § 640.84(a) and (c) for Albumin; § 640.94(a) for Plasma Protein Fraction; § 660.2(c) for Antibody to Hepatitis B Surface Antigen; § 660.28(a) and (b) for Blood Grouping Reagent; § 660.35(a), (c through g), and (i through m) for Reagent Red Blood Cells; § 660.45 for Hepatitis B Surface Antigen; and § 660.55(a) and (b) for Anti-Human Globulin. The burden associated with the additional labeling requirements for submission of a license application for these certain biological products is minimal because the majority of the burden is associated with the requirements under § 610.60 through § 610.62 or § 809.10. Therefore, the burden estimates for these regulations are included in the estimate under § 610.60 through § 610.62 in table 1 of this document. The burden estimates associated with § 809.10 are approved under OMB control number 0910–0485 (expires June 30, 2008).

Section 601.25(b) requests interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of biological products that have been licensed prior to July 1, 1972. Section 601.26(f) requests that licensees submit to FDA a written statement intended to show that studies adequate and appropriate to resolve questions raised about a biological product have been undertaken for a product if designated as requiring further study under the reclassification procedures. Under § 601.25(b)(3), FDA estimates no burden for this regulation since all requested data and information had been submitted by 1974. Under § 601.26(f), FDA estimates no burden for this regulation since there are no products designated to require further study and none are predicted in the future. However, based on the possible reclassification of a product, the labeling for the product may need to be revised, or a manufacturer, on its own initiative, may deem it necessary for further study. As a result, any changes to product labeling would be reported under § 601.12.

Section 601.27(a) requires that applications for new biological products contain data that are adequate to assess the safety and effectiveness of the biological product for the claimed indications in pediatric subpopulations, and to support dosing and administration information. Section 601.27(b) provides that an applicant may request a deferred submission of some or all assessments of safety and effectiveness required under § 601.27(a). Section 601.27(c) provides that an applicant may request a full or partial waiver of the requirements under § 601.27(a). The burden estimates for § 601.27(a) are included in the burden estimate under § 601.2(a) in table 1 of this document, since these regulations deal with information to be provided in an application.

Section 601.28 requires sponsors of licensed biological products to submit the information in § 601.28(a), (b), and (c) to the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research (CDER) each year, within 60 days of the anniversary date of approval of the license. Section 601.28(a) requires sponsors to submit to FDA a brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Section 601.28(b) requires sponsors to submit to FDA an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. Section 601.28(c) requires sponsors to submit to FDA a statement on the current status of any postmarketing studies in the pediatric population performed by, or on behalf of, the applicant. If the postmarketing studies were required or agreed to, the status of these studies is to be reported under § 601.70, rather then under this section.

Sections 601.33 through 601.35 clarify the information to be submitted in an application to FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals. The burden estimates for §§ 601.33 through 601.35 are included in the burden estimate under § 601.2(a) in table 1 of this document, since these regulations deal with information to be provided in an application.

Section 601.70(b) requires each applicant of a licensed biological product to submit annually a report to FDA on the status of postmarketing studies for each approved product application. Each annual postmarketing status report must be accompanied by a completed transmittal Form FDA 2252 (approved under OMB control number 0910–0001). Under § 601.70(d), two copies of the annual report shall be submitted to FDA.

Section 601.91(b)(3) requires applicants to prepare and provide labeling with relevant information to patient or potential patient for biological products approved under the subpart when human efficacy studies are not ethical or feasible (or based on evidence of effectiveness from studies in animals). Section 601.93 provides that biological products approved under this subpart are subject to the postmarketing recordkeeping and safety reporting applicable to all approved biological products. Section 601.94 requires applicants under this subpart to submit to the agency for consideration during preapproval review period copies of all promotional materials including promotional labeling as well as advertisements. Under § 601.93, any potential postmarketing reports and/or recordkeeping burdens would be included under the adverse experience reporting (AER) requirements under 21 CFR part 600 (OMB control number 0910–0308; expires May 31, 2005). Therefore, any burdens associated with these requirements would be reported under the AER information collection requirements (OMB control number 0910–0308).

Section 610.11(g)(2) (21 CFR 610.11(g)(2)) provides that a

manufacturer of certain biological products may request an exemption from the general safety test (GST) requirements contained in this subpart. Under § 610.11(g)(2), FDA requires only those manufacturers of biological products requesting an exemption from the GST to submit additional information as part of a license application or supplement to an approved license application. Therefore, the burden estimate for § 610.11(g)(2) is included in the estimate under §§ 601.2(a) and 601.12(b) in table 1 of this document.

Section 610.67 requires certain biological products to comply with the bar code requirements at § 201.25 (21 CFR 201.25). Section 201.25 is approved under OMB control number 0910–0537 (expires February 28, 2007).

Section 680.1(c) requires manufacturers to update annually their license file with the list of source materials and the suppliers of the materials.

Sections 600.15(b) and 610.53(d) require the submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. Section 606.110(b) requires the submission of a request for approval to perform plasmapheresis of donors who do not meet certain donor requirements for the collection of plasma containing rare antibodies. Under §§ 600.15(b), 610.53(d), and 606.110(b), a request for an exemption or modification to the requirements would be submitted as a supplement. Therefore, the burden hours for any submissions under §§ 600.15(b), 610.53(d), and 606.110(b) are included in the estimates under § 601.12(b) in table 1 of this document.

In July 1997, FDA revised Form FDA 356h ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use'' to harmonize application procedures between CBER and CDER. The application form serves primarily as a checklist for firms to gather and submit certain information to FDA. The checklist helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. The form provides key information to FDA for efficient handling and distribution to the appropriate staff for review. The estimated burden hours for submissions to CDER using Form FDA 356h are reported under OMB control number 0910–0001.

Form FDA 2567 ''Transmittal of Labels and Circulars'' is used by manufacturers of licensed biological products to submit labeling (e.g., circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. The labeling information is submitted with the form for license applications, supplements, or as part of an annual report. Form FDA 2567 is also used for the transmission of advertisements and promotional labeling. Form FDA 2567 serves as an easy guide to assure that the manufacturer has provided the information required for expeditious handling of their labeling by CBER. For advertisements and promotional labeling, manufacturers of licensed biological products may submit to CBER either Form FDA 2567 or 2253. Form FDA 2253 was previously used only by drug manufacturers regulated by CDER. In August 1998, FDA revised and harmonized Form FDA 2253 so the form may be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The revised, harmonized form updates the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or labeling submitted; clarifies the intended audience for the advertisements or promotional labeling (e.g., consumers, professionals, news services); and helps ensure that the submission is complete.

Under table 1 of this document, the number of respondents is based on the estimated annual number of manufacturers that submitted the required information to FDA or the number of submissions FDA received. Based on information obtained from FDA's database systems, there are an estimated 306 licensed biologics manufacturers. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total annual responses are based on the estimated number of submissions (i.e., license applications, labeling and other supplements, protocols, advertising and promotional labeling, notifications) for a particular product received annually by FDA. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry and past FDA experience with the various submissions or notifications. The hours per response include the time estimated to prepare the various submissions or notifications to FDA, and, as applicable, the time required to fill out the appropriate form and collate the documentation. Additional information regarding these estimates is provided below as necessary.

Under §§ 601.2 and 601.12, the estimated hours per response are based on the average number of hours to submit the various submissions. The estimated average number of hours is based on the range of hours to complete a very basic application or supplement and a complex application or supplement.

Under § 601.6(a), the total annual responses are based on FDA estimates that establishments may notify an average of 20 selling agents and distributors of such suspension, and provide FDA of such notification. The number of respondents is based on the estimated annual number of suspensions of a biologic license.

Under §§ 601.12(f)(4) and 601.45, manufacturers of biological products may use either Form FDA 2567 or Form FDA 2253 to submit advertising and promotional labeling. Based on information obtained from FDA's database system, there were an estimated 3,600 submissions of advertising and promotional labeling in fiscal year 2004. FDA estimates that approximately 15 percent of those submissions were received with Form FDA 2567 resulting in an estimated 540 submissions. The burden hours for the remaining submissions received using Form FDA 2253 are reported under OMB control number 0910–0001.

Under § 601.70(b), FDA estimates that it takes an applicant approximately 24 hours (8 hours per study x 3) annually to gather, complete, and submit the appropriate information for each postmarketing status report (approximately two to four studies per report) and the accompanied transmittal Form FDA 2252. Included in these 24 hours is the time necessary to prepare and submit two copies of the annual progress report of postmarketing studies to FDA under § 601.70(d).

Under §§ 601.91 through 601.94, FDA expects to receive very few applications of this nature; however, for calculation purposes, FDA is estimating the annual submission of one application. Under §§ 601.93(b)(3) and 601.94, FDA estimates 240 hours for a manufacturer of a new biological product to develop patient labeling, and to submit the appropriate information and promotional labeling to FDA. The majority of the burden for developing the patient labeling is included under the reporting requirements for § 601.94, therefore minimal burden is calculated for providing the guide to patients under § 601.91(b)(3).

There were also 3,540 amendments to an unapproved application or supplement and 23 resubmissions (total of 3,563 submissions) submitted using Form FDA 356h.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.2(a),[2] 610.60, 610.61, and 610.62[3]	2567/356h	14	2	28	860	24,080
601.5(a)	NA	16	3.13	50	.33	17
601.6(a)	NA	1	21	21	.33	7
601.12(a)(5)	NA	190	15.7	2,983	1	2,983
601.12(b)(1)/(b)(3)[4]	356h[2]	190	4.75	903	80	72,240
601.12(c)(1)/(c)(3[5]	356h[2]	98	2.60	255	50	12,750
601.12(c)(5)	356h[2]	34	1.38	47	50	2,350
601.12(d)(1)/(d)(3)	356h[2]	166	1.37	227	22.5	5,107.5
601.12(e)	356h[2]	14	1.43	20	120	2,400
601.12(f)(1)[6]	2567	12	1	12	40	480
601.12(f)(2)[6]	2567	10	1	10	20	200
601.12(f)(3)[7]	2567	70	1.43	100	10	1,000
601.12(f)(4)/601.45	2567	15	36	540	10	5,400
601.25(b)(3)	NA	0	0	0	0	0
601.26(f)	NA	0	0	0	0	0
601.27(b)	NA	3	1	3	24	72
601.27(c)	NA	7	1	7	8	56
601.28(a), (b), and (c)	NA	44	3.27	144	33.5	4,824
601.70(b) and (d)	2252	19	1.58	30	24	720
601.91(b)(3), 601.94	NA	1	1	1	240	240
610.67	NA	174	31	5,400	24	129,600
680.1(c)	NA	10	1	10	2	20
Amendments/Resubmissions	356h	306	11.6	3,563	20	71,260
Total						335,806.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The reporting requirements under §§ 601.14, 601.27(a), 601.33, 601.34, 601.35, 610.11(g)(2), 640.17, 640.25(c), 640.56(c), 640.74(b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) are included in the estimate under § 601.2(a).
[3]The reporting requirements under §§ 640.70(a), 640.74(b)(3), and (b)(4), 640.84(a) and (c), 640.94(a), 660.2(c), 660.28(a) and (b), 660.35(a), (c through g), and (i through m), 660.45, and 660.55(a) and (b) are included under § 610.60 through 610.62.
[4]The reporting requirements under §§ 600.15(b), 610.11(g)(2), 610.53(d), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), and 680.1(d) are included in the estimate under § 601.12(b).
[5]The reporting requirements under §§ 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) are included in the estimate under § 601.12(c).
[6]The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(1) and (f)(2).
[7]The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(3).

Under table 2, the estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
601.91(b)(2)(iii)	1	1	1	1	1

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18445 Filed 11–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Cellular, Tissue and Gene Therapies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held by teleconference on November 20, 2006, from 2:15 p.m. to approximately 5 p.m.

Location: National Institutes of Health (NIH), Bldg. 29, rm. 121, 9000 Rockville Pike, MD. This meeting will be held by teleconference. The public is welcome to attend the meeting at the specified location. A speakerphone will be provided at the specified location for public participation in the meeting. Important information about transportation, directions to the NIH campus, parking, and security procedures is available on the Internet at *http://www.nih.gov/about/visitor/index.htm*. Visitors must show two forms of identification, one of which must be a Government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and park on the NIH campus, you must enter at the South Dr. entrance of the campus which is located on Wisconsin Ave. (the Medical Center Metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located at *http://www.nih.gov/about/visitorsecurity.htm*. Due to the limited available parking, visitors are encouraged to use public transportation. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Contact Person: Gail Dapolito or Rosanna Harvey, Center for Biologics Evaluation and Research, (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD, 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 20, 2006, the committee will meet in open session to hear updates of research programs in the Laboratory of Immunobiology and the Laboratory of Immunology, Office of Biotechnology Products, Center for Drug Evaluation and Research.

Procedure: On November 20, 2006, from 2:15 p.m. to approximately 4:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 13, 2006. Oral presentations from the public will be scheduled between approximately 3:30 p.m. and 4:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 13, 2006.

Closed Committee Deliberations: On November 20, 2006, from approximately 4:30 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss a report of intramural research programs.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 27, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning

[FR Doc. E6–18472 Filed 11–1–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 6, 2006, from 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.